

K980887 ELECSYS CEA ON THE ELECSYS 1010Jun 29, 1998
112 days to decisionK980887 · Product code: **DHX** · Immunology
Source: <https://www.510kdatabase.net/k980887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Mar 9, 1998
Decision date	Jun 29, 1998
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boehringer Mannheim Corp.
Location	Mchenry, IL, US
Contact	Patricia M Klimley
510(k) history	340 submissions · 340 cleared · 1976-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980887/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026